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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/760,506	01/12/2001	Charlotte Kensil	106941.190	2171

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EXAMINER

QIAN, CELINE X

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 07/02/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/760,506

Applicant(s)

KENSIL, CHARLOTTE

Examiner

Celine X Qian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31,33-38,40 and 44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31,33-38,40 and 44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 April 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>16</u> | 6) <input type="checkbox"/> Other: |

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DETAILED ACTION

Claims 31, 33-38, 40 and 44 are pending in the application.

This Office Action is in response to the Amendment filed on 4/23/03.

Response to Amendment

Acknowledgment is made of applicant's submission of corrected drawing.

The rejection of claims 31, 33-38 and 40 under 35 U.S.C. 112 1st paragraph (written description) has been withdrawn in light of Applicants' amendment of the claims.

The rejection of claims 31-34, 37, 39 and 40 under 35 U.S.C. 102 (b) has been withdrawn in light of Applicants' amendment of the claims.

The rejection of claims 35-36 under 35 U.S.C. 103 (a) has been withdrawn in light of Applicants' amendment of the claims.

Claims 31, 33-38, 40 and newly added claim 44 remain rejected under 35 U.S.C. 112 2nd paragraph for reasons set forth of the record and further discussed below.

Claims 31, 33-38, 40 and newly added claim 44 are rejected under 35 U.S.C. 112 1st paragraph for reasons discussed below.

Response to Arguments

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 31, 33-38, 40 and 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 31, 33-38, 40 and 44 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: how to determine cancer is treated.

In response to the rejection, Applicants argue that claims are definite because the exact methods used to determine immunity is unimportant, hence not essential steps to practice the method.

Applicants' argument has been fully considered but deemed unpersuasive. While it is not necessary to recite the exact method steps of treating cancer, the method is not considered complete if the method steps do not refer back to the preamble "a method of treating cancer." Appropriate correction is required.

New Grounds of Rejection Necessitated by Applicants' Amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 31, 33-38, 40 and 44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not

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described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to: (a) the breadth of the claims; (b) the nature of the invention; (c) the state of the prior art; (d) the relative skill of those in the art; (e) the level of predictability in the art; (f) the amount of direction provided by the inventor; (g) the existence of working examples; and (h) whether the quantity of experimentation needed to make or use the invention based on the content of the disclosure is "undue" (MPEP 2164.01 (a)).

The nature of the invention:

The claims are drawn to a method of treating cancer by administering an effective amount of a composition comprising a *Quillaja saponaria* saponin to an individual to stimulate innate immunity. The claims are further drawn to a method of treating cancer by using chemically modified *Quillaja saponaria* saponin (claim 33).

The breadth of the claim:

The claims encompass a method for treating any type of cancer by administering *Quillaja saponaria* saponin to an individual. The claims also encompass treating cancer by administering any type of chemically modified saponin isolated from *Quillaja saponaria*.

The teaching of the specification and working examples:

The teaching of the specification is limited. The specification only teaches a method of stimulate an innate immune response in a mouse by using saponins isolated from *Quillaja*

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saponaria. The specification fails to teach whether other saponins, for example, a chemically modified saponin, can stimulate innate immune response in an individual. The specification fails to teach whether *Quillaja saponaria* saponin or any chemically modified saponin is effective in treating any type of cancer.

The state of the prior art and the level of predictability in the art:

The state of art at the time of filing teaches that *Quillaja saponaria* saponin can potentiating innate immune response and is useful as vaccine adjuvant. The prior art also teach that saponins isolated from different source possess different chemical structures which affect their biological activity. Although some saponins such as soybean saponins have been reported to have anti-carcinogenic activity in cell culture and mice models, there is no report to date that they are clinically effective in treating cancer. Further, there is no report that *Quillaja saponaria* saponin has anti-tumor activity. As such, whether administering *Quillaja saponaria* saponin or chemically modified *Quillaja saponaria* saponin to an individual can treat cancer is unpredictable. In fact, the mere demonstration of increasing natural killer cell activity by *Quillaja saponaria* saponin does not provide sufficient support for its anti-tumor activity. In addition, there is no single agent known can treat all types of cancer. As such, whether administering *Quillaja saponaria* saponin to an individual can treat any type of cancer is unpredictable.

In summary, the specification fails to teach a method of treating a single type of cancer by using *Quillaja saponaria* saponin or any of its chemically modified form either *in vivo* or *in vitro*. The specification fails to provide any working example that demonstrates the effectiveness of *Quillaja saponaria* saponin in treating cancer. In view of limited teaching in the specification

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and unpredictability in the art, one skilled in the art would have to engage in undue experimentation to practice the method as claimed.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 703-306-0283. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 703-305-1998. The fax phone numbers for the

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organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Celine Qian, Ph.D.
June 27, 2003



JAMES KETTER
PRIMARY EXAMINER